PTO/SB/08A (08-03) Approved for use through 07/31/2006. OMB 0651-0031

U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

k Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number. Complete if Known Substitute 10 Application Number 10/796.529 INFORMATION DISCLOSURE Filing Date March 8, 2004 STATEMENT BY APPLICANT First Named Inventor Schinazi, et al. Group Art Unit Unassigned (use as many sheets as necessary) Examiner Name Unassigned Attorney Docket Number 18085.105232 EMU 2000 CON2 Sheet 4

3461245 3.DOC

						3461245_3.DO
				U.S. PATENT DOCUMENTS		-
Examiner nitials *	Cite No. 1		ument Kind Code f known)	Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages o Relevant Figures Appear
JR	AA	4,000,137	A	Dvonch, et al.	12-28-1976	
	AB	4,211,773	A	Lopez et al.	07-08-1980	
	AC	4,336,381	Α	Nagata et al.	06-22-1982	
	AD	4,625,020	Α	Brundidge et al.	11-25-1986	
	AE	4,666,892	Α	Fox et al.	05-19-1987	-
	AF	4,908,440	A	Sterzycki, et al.	03-13-1990	
	AG	5,034,518	A	Montgomery et al.	07-23-1991	
	AH	5,128,458	Α	Montgomery et al.	07-09-1992	
	AI	5,210,085	Α	Liotta, et al.	05-11-1993	· · · · · · · · · · · · · · · · · · ·
	AJ	5,246,924	Α	Fox et al.	09-21-1993	
	AK	5,424,416	Α	Jones et al.	06-13-1995	
	AL	5,426,183	Α	Kjell et al.	06-20-1995	
	AM	5,446,029	Α	Eriksson et al.	08-29-1995	
	AN	5,512,671	Α	Piantodosi et al.	04-30-1996	
	AO	5,565,438	Α	Chu et al.	10-15-1996	
	AP	5,567,688	Α	Chu et al.	10-22-1996	
	AQ	5,587,362	A	Chu et al.	12-24-1996	
	AR	5,703,058	Α	Schinazi et al.	12-30-1997	
	AS	5,808,040	A	Chu, et al.	09-15-1998	· · · · · · · · · · · · · · · · · · ·
	AT	5,817,799	Α	Marquez, et al.	10-06-1998	
	AU	5,886,162	Α	Kalman et al.	03-23-1999	
	AV	5,905,070	Α	Schinazi et al.	05-18-1999	
	AW	6,103,707	Α	Yamada, et al.	08-15-2000	
	AX	6,147,058	Α	Yoshimura, et al.	11-14-2000	
	AY	6,232,300	Bl	Schinazi, et al.	05-15-2001	
	AZ	6,348,587	Bl	Schinazi et al.	02-19-2002	
	AAA	6,407,077	Bl	Gosselin, et al.	06-18-2002	
	AAB	6,458,773	Bl	Gosselin, et al.	10-01-2002	
JR	AAC	2002-0198171	Al	Schinazi et al.	12-26-2002	

Examiner Signature /Jezia Riley/ Date Consider	ered 09/17/2006
--	-----------------

^{*}EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Unique citation designation number. ² See attached Kinds of U.S. Patent Documents. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁶ Applicant is to place a check mark here if English language Translation is attached.

PTO/SB/08A (08-03) Approved for use through 07/31/2006. OMB 0651-003

U.S. Patern and Trademark Office: U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control

Subst	itute for form 1449A/PTO			Complete if Known		
				Application Number	10/796,529	
	FORMATION I			Filing Date	March 8, 2004	
ST	ATEMENT BY	APPL	ICANT	First Named Inventor	Schinazi, et al.	
	(use as many sheets	·	1	Group Art Unit	Unassigned	
	(use as many sneed	s as necessi	ary)	Examiner Name	Unassigned	
Sheet	2	of	4	Attorney Docket Number	18085.105232 EMU 2000 CON	

3461245 3.DOC FOREIGN PATENT DOCUMENTS Foreign Patent Document Date of Pages, Columns, Cite Examiner Name of Patentee or Applicant of Cited Publication of Lines, Where Relevant Office Number Kind Code Initials * No. 1 Document Cited Document Passages or Relevant Tو MM-DD-YYYY Figures Appear JR BA EP 0,292,023 **A2** Hoffman-LaRoche 05-24-1988 BB EP 0,316,017 **A2** Sterzycki et al. 05-17-1989 BC **EP** 0,357,571 **B**1 Medivir Aktiebolag 04-03-1996 BD EP 0,382,526 **A2** IAF Biochem International 08-18-1990 BE EP 0,409,227 **A2** Akad. Wissenschaften der DDR 01-23-2991 0,463,470 **A2** BF EP Hoffman-LaRoche 01-02-1992 BG EP 0,839,813 A1 Yamasa Corp. 05-06-1998 BH WO 88/08001 Aktiebolaget Astra Αl 10-20-1988 ΒI WO 91/11186 Αl **Emory University** 08-08-1991 BJ WO 92/08727 Αl Consig. Naz. Ricerche 05-29-1992 BK WO 92/14743 A2 Emory University 09-03-1992 BL WO 07-07-1994 94/14831 Αl Univ. of Alberta BM WO 95/20595 Αl Univ. Georgia Res. Found., Yale Univ. 08-03-1995 BN WO 96/22778 Al **Emory University** 08-01-1996 96/40164 BO WO A1 Emory Univ.; UAB R.F.; C.N.R.S 12-19-1996 BPwo 97/28177 A1 Amersham International P.L.C. 08-07-1997 BQ WO 97/37993 A1 Yamasa Corporation 10-16-1997 BR WO 98/18430 **A2** Univ. North Carolina Chapel Hill 05-07-1998 JR BS WO 99/43691 A1 Emory Univ.; Univ. Georgia R. F. 09-02-1999

Examiner Signature	/Jezia Riley/	Date Considered	09/17/2006

^{*}EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Unique citation designation number. ² See attached Kinds of U.S. Patent Documents. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ³ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁶ Applicant is to place a check mark here if English language Translation is attached.

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMR control number.

		***************************************	ract or 1775, the persons	are required to respond to a confection	in of information unless it comains a valid OMB control number.	
Substitut	te for form 1449A/PTO			Complete if Known		
	0D14.MT01-			Application Number	10/796,529	
	ORMATION D		-	Filing Date	March 8, 2004	
SIA	TEMENT BY	APPLI	ICANT	First Named Inventor	Schinazi, et al.	
	(use as many sheets t	at necesta	en l	Group Art Unit	Unassigned	
	(the the many section)	as necessar	<i>y</i> /	Examiner Name	Unassigned	
Sheet	3	of	4	Attorney Docket Number	18085.105232 EMU 2000 CON	

3461245_3.DOC

		OTHER REION ART. NON BATCHT LITERATURE ROCHMENTS			
	1	OTHER PRIOR ART – NON PATENT LITERATURE DOCUMENTS			
Examiner Initials •	Cite Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journs No. serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.		T ⁶		
TD	CA	BALAKRISHNA, P.S., et al., "Inhibition of Hepatitis B. Virus by a Novel L-Nucleoside,			
JR		2'-Fluoro-5-MenthylL- arabinofuranosyl Uracil," Antimicrobial Agents and Chemotherapy, 40(2):380-386 (February 1996).			
JR	СВ	BORTHWICK, et al., "Synthesis and Enzymatic Resolution of Carbocyclic 2'-Ara-fluoro-Guanosine; A Potent New Anti-Herpetic Agent," J. Chem Soc., Chem. Commun., (1988).			
JR	CC	BOUFFARD, D.Y., et al., "Kinetic Studies of 2',2'-Difluorodeoxycytidine (Gemcitabine) with Purified Human Deoxycytidine Kinase and Cytidine Dearminase," <i>Biochemical Pharmacology</i> , 45(9):1857-1861 (May 5, 1993).			
JR	CD	CHENG, et al., "Deoxycytidine deaminase-resistant stereoisomer is the active form of (+/-)-2',3'-dideoxy-3'-thiacytidine in the inhibition of hepatitis B virus replication," Journal of Biological Chemistry, Volume 267(20):13938-13942 (July 1992).			
JR	CE	CHU, et al., "Use of 2'-Fluoro-5-methylL-arabinofuranosyluracil as a Novel Antiviral Agent for Hepatitis B. Virus and Epstein-Barr Virus" Antimicrobial Agents and Chemotherapy, 39(4):979-981 (April 1995).			
-	CF	FURMAN, et al., "The Anti-Hepatitis B. Virus Activities, Cytotoxicities, and Anabolic Profiles of			
JR		the (-) and (+) Enantiomers of cis-5-Fluoro-1[2-(Hydroxymethyl)-1, 3-oxathiolane-5-yl]-Cytosine" Antimicrobial Agents and Chemotherapy, 36(12):2686-2692 (December 1992).			
JR	CG	JEONG, L.S., et al., "Facile Fluorination of Deoxy-4'-thiopyrimidine Nucleosides with 'Down' Hydroxyl Groups. Retention of Configuration After Fluoride Opening of the Quaternized N ³ -MEM Anhydronucleosides," Tetrahedron Letters, 35(41):7573-7576 (1994).			
	СН	JEONG, L.S., et al., "Unanticipated Retention of Configuration in the DAST Fluorination of Deoxy-			
JR		4'-thiopyrimidine Nucleosides with 'Up' Hydroxyl Groups," <i>Tetrahedron Letters</i> , 35(41):7569-7572 (1994).			
	CI	MACHIDA, H., et al., "Anti-herpesvirus activity profile of 4'-thioarabinofuranosyl purine and uracil			
JR		nucleosides and activity of 1-beta-D-2'-fluoro-4'-thioarabinofuranosyl guanine and 2,6-diaminopurine against clinical isolates of human cytomegalovirus." <i>Antiviral Res.</i> , 39(2):129-137 (August, 1998).			
JR	CJ	MARQUEZ, V.E., et al., Nucleosides & Nucleotides, 14(3-5):555-558 (1995).			
	CK	MARTIN, et al., "Synthesis and Antiviral Activity of Monofluoro and Difluoro Analogues of			
JR		Pyrimidine Deoxyribonucleosides against Human Immunodeficiency Virus (HIV-1), J. Med., Chem., 33:2137-2145 (1990).			

Examiner	/Tomic Diless/	Date	09/17/2006
Signature	/Jezia Riley/	Considered	

^{*}EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Unique citation designation number. ² See attached Kinds of U.S. Patent Documents. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ³ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁶ Applicant is to place a check mark here if English language Translation is attached.

U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number. Complete if Known Substitute for form 1449A/PTO Application Number 10/796-529 INFORMATION DISCLOSURE Filing Date March 8, 2004 STATEMENT BY APPLICANT First Named Inventor Schinazi, et al. **Group Art Unit** Unassigned (use as many sheets as necessary) **Examiner Name** Unassigned Attorney Docket Number 18085.105232 EMU 2000 CON Sheet

3461245 3.DOC

		3461245_3	.DUC		
		OTHER PRIOR ART – NON PATENT LITERATURE DOCUMENTS			
Examiner Initials *	Cite No. 1	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ⁶		
JR	DA	MONTGOMERY, J.A., et al., "9-(2-Deoxy-2-fluoro-β-D-arabinofuranosyl)guanine: A Metabolically Stable Cytotoxic Analogue of 2'-Deoxyguanosine," J. Med. Chem., 29(11):2389-2392 (November 1986).			
JR	DB	NIIHATA, S., et al., "Synthesis of 2-Fluoro Sugar and Its Condensation Reaction with Silylated Thymine," Bull. Chem. Soc. Jpn. 68(5):1509-1512 (May 1995).			
JR	DC	OKABE, M., et al., "Synthesis of 1-(2,3-Dideoxy-2-fluoro-β-D-threo-pentofuranosyl)cytosine (F-ddC). A Promising Agent for the Treatment of Acquired Immune Deficiency Syndrome," J. Org. Chem. 56:4392-4397 (February 1991).			
JR	DD	SCHINAZI, et al., "Selective Inhibition of Human Immunodefiency viruses by Racemates and Enantiomers of cis-5-Fluoro-1-2[Hydroxymethyl)-1, 3-Oxathiolane-5-yl]Cytosine" Antimicrobial Agents and Chemotherapy, 36(11): 2423-2431 (November 1992).			
JR	DE	SCHINAZI, et al., Mutations in retroviral genes associated with drug resistance, International Antiviral News (1997).			
JR	DF	SIDDIQUI, M.A., et al., "A New Synthetic Approach to the Clinically Useful, Anti-HIV Active Nucleoside, 9-(2,3-Dideoxy-2-fluoro-beta-D-threo-pentofuranosyl)adenine (beta-FddA). Introduction of a 2'-beta-Fluoro Substituent via Inversion of a Readily Obtainable 2'-alpha-Fluoro Isomer," Tetrahedron Letters, 39(13):1657-1660 (March 26, 1998).			
JR	DG	STERZYCKI, et al., "Synthesis and Anti-HIV Activity of Several 2'-Fluoro-Containing Pyrimidine Nucleosides," J. Med. Chem., 33(8):2150-2157 (August 1990).	-		
JR	DH	SU, T.S., et al., "Sythesis and Antiviral Effects of Several 1-(2-Deoxy-2-fluoro-B-D-arabinofuranosyl)-5-alkyluracils. Some Structure-Activity Relationships," J. Med. Chem., 29:151-154 (1986).			
JR	DI	TOYOTA, A., et al., Tetrahedron, 51(32):8783-8798 (1995).			
JR	DJ	Van AERSCHOT, A., et al., "3'-Fluoro-2',3'-dideoxy-5-chlorouridine: Most Selective Anti-HIV-1 Agent among a Series of New 2'- and 3'-Fluorinated 2',3'-Dideoxynucleoside Analogues.", J. Med. Chem. 32(8):1743-1749 (August 1989).			
JR	DK	WANTANABE, et al., "Synthesis and Anti-HIV Activity of 2'-"Up"-Fluoro Analogues of Active Anti-Aids Nucleosides 3'-Azido-3'deoxythymidine (AZT) and 2', 3'-dideoxycytidinee (DDC)," J. Med. Chem., 33:2145-2150 (1990).			
JR	DL	YOAHIMURA, Y., et al., J. Org. Chem., 64:7912-7920 (1999).			

JR

Examiner Signature	/Jezia Riley/	Date Considered	09/17/2006

^{*}EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Unique citation designation number. ² See attached Kinds of U.S. Patent Documents. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ³ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁶ Applicant is to place a check mark here if English language Translation is attached.